

**Amendments to the Specification:**

Please amend the paragraph beginning on page 4, line 7 as follows:

The first-level alarm condition is triggered in response to a pressure drop in the system to less than or equal to a specified system pressure. A system pressure is the fluid pressure in at least one portion of the system. Preferably the relevant pressure for triggering a first-level alarm is the system pressure at the inlet pump. ~~The first-level alarm pauses fluid flow in at least a portion of the system.~~ In one embodiment, the first alarm condition comprises pausing the fluid flow in at least a portion of the system for a specific delay time. In an exemplary embodiment, the first alarm condition comprises pausing the fluid flow in at least a portion of the system for a delay time of about 2 seconds to about 6 seconds. Preferably, in a blood apheresis system comprising a leukocyte reduction chamber, the platelet pump is not paused, as this will allow fluid flow to be maintained through the leukocyte reduction chamber.

Please amend the paragraph beginning on page 5, line 24 as follows:

The specified system pressure generally is not directly sensed at a pressure sensor. The pressure registered at the sensor is affected by certain system parameters. Selected system parameters are therefore used to calculate a sensor pressure which will trigger a first-level alarm. This calculated sensor pressure is based on a specified system pressure and selected system parameters including ~~inlet pump hematocrit, ratio of anticoagulant to whole blood in an inlet line of the system during platelet and plasma collection, inlet pump flow rate, and donor hematocrit,~~ a configuration specified system pressure, the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle and the hematocrit in the needle.

Please amend the paragraph beginning on page 6, line 1 as follows:

In one embodiment, the sensor pressure which triggers the first-level alarm is calculated using the formula:

$$P_{AAL} = P_{AALS} + 75 - 0.331 Q_{ININSTD} / (1 - H_{IN}) - 0.303 Q_{ININSTD} (1 - 1/R) / (1 - H) - 350$$

where  $P_{AAL}$  is the specified sensor pressure that triggers the first-level alarm;  $P_{AALS}$  is the specified first-level alarm triggering system pressure, mmHg;  $H_{IN}$  is inlet pump hematocrit, decimal;  $Q_{ININSTD}$  is instantaneous inlet pump flow rate (during the draw phase), ml/min; and  $R$  is ratio of whole blood to anticoagulant in an inlet line of said system during platelet and plasma collection.

specified sensor pressure = Config + 75 - 0.3309 \*  $Q_{in}$ /(1- $H_{in}$ ) - 0.3026 \*  $Q_n$ /(1- $H_n$ );

where Config is a configuration specified system pressure (mmHg.),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle. Alternatively, the sensor pressure which triggers the first-level alarm may be calculated using the formula:

specified sensor pressure = Config + 75 - 0.3309 \*  $Q_{in}$ /(1- $H_{in}$ ) - 0.5602 \*  $Q_n$ /(1- $H_n$ );

where Config is a configuration specified system pressure (mmHg.),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.

Please delete the entire paragraph beginning on page 6, line 18 which starts with the recitation "The specified first-level alarm-disabling sensor pressure."

Please amend the paragraph beginning on page 6, line 28 and ending on page 7, line 17 as follows:

This method comprises specifying a system return-flow alarm-triggering pressure, and when pressure of the system return flow is higher than or equal to this pressure, triggering a return-flow alarm which stops the return flow pump and preferably sounds an audible alarm and/or displays a visible alarm. The sensor pressure which triggers the return-flow alarm is preferably measured at the same location as the sensor pressure which triggers the first-level alarm, just upstream of the inlet pump. Again, the sensor pressure which triggers the return-flow alarm is generally not the same as the specified system return-flow alarm-triggering pressure because the value shown by the sensor is not the same as the pressure in the system. This sensor pressure for triggering the return-flow alarm may be calculated using the specified system return-flow alarm-triggering pressure and selected system parameters including ~~return pump flow, return pump hematocrit, return needle flow rate, and return needle hematocrit, a configuration specified system pressure, the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle and the hematocrit in the needle.~~ Preferably the sensor pressure for triggering the return-flow alarm condition is calculated using the formula:

$$P_{RAL} = P_{RALS} - 50 - 0.3331 Q_{ININSTR} / (1 - H_{IN}) - 0.303 Q_{NRET} / (1 - H_{NRET}) - 400$$

~~where  $P_{RAL}$  is the sensor pressure that triggers the return-pressure alarm, mmHg;  $P_{RALS}$  is the specified system return-flow alarm-triggering pressure, mmHg;  $Q_{ININSTR}$  is return pump flow, ml/min;  $H_{IN}$  is return pump hematocrit, decimal;  $Q_{NRET}$  is the flow rate through the needle during the single needle return phase, ml/min; and  $H_{NRET}$  is the hematocrit of the flow through the return needle.~~

specified sensor pressure = Config - 50 - 0.3309 \*  $Q_{in}$ /(1- $H_{in}$ ) - 0.3026 \*  $Q_n$ /(1- $H_n$ );

where Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle. Alternatively, the

sensor pressure for triggering the return-flow alarm condition is calculated using the formula:

$$\text{specified sensor pressure} = \text{Config} - 50 - 0.3309 * Q_{in}/(1-H_{in}) - 0.5602 * Q_n/(1-H_n);$$

where Config is a configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.

Please insert the following new paragraph on page 9, between lines 24 and 25:

In one embodiment the present invention provides a method for controlling a fluid separation system comprising the steps of: (1) triggering a first-level alarm condition in response to a pressure drop to less than or equal to a specified system pressure, said first alarm condition comprising pausing fluid flow in at least a portion of said system for a specified delay time; and (2) triggering a second alarm condition in response to a specified number of said pressure drops within a specified period, said second alarm condition comprising reducing flow rate of fluid in said system. Optionally, this method the present invention may further comprise the step of triggering a third alarm condition in response to failure of pressure in the system to rise to a specified first-level alarm-disabling pressure in the system. In another embodiment, the present invention comprises a method for controlling an apheresis system comprising the steps of: (1) triggering a first alarm condition in response to a specified pressure drop to less than or equal to a specified pressure in the system, said first alarm condition comprising pausing fluid flow in at least a portion of said system for a specified delay time; (2) if plasma and platelet collection is incomplete, triggering a second-level alarm condition in response to a specified number of said specified pressure drops within a specified period, said second alarm condition comprising reducing flow rate of fluid in said system; and (3) if plasma and platelet collection is complete, triggering a third-level alarm condition in response to a selected number of said selected pressure drops

within a specified period, said third-level alarm condition comprising stopping all pumps. In yet another embodiment, the present invention provides a method for controlling flow rate of return of fluid to a fluid source in a fluid separation process wherein components have been separated from said fluid, said method comprising the step of specifying a system return-flow alarm-triggering pressure, and when pressure of said return flow in the system is higher than or equal to said specified pressure, triggering a return-flow alarm.

Please amend the paragraph beginning on page 29, line 8 as follows:

A first-level alarm is triggered when the inlet pressure measured by the sensor is below a specified sensor pressure. This specified sensor pressure is calculated as a function of the specified system pressure which would trigger a first-level alarm, and the following parameters: ~~instantaneous inlet pump flow during the draw phase, inlet pump hematocrit, anticoagulant (AC) ratio during platelet and plasma collection, and donor hematocrit,~~ a configuration specified system pressure, the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle and the hematocrit in the needle. A calculation is necessary because the pressure readout from the sensor, which is preferably located just upstream from the inlet pump, may not be the same as the actual pressure in the system. The lower threshold of the specified sensor pressure is calculated in accordance with the following formula useful for the Gambro Trima® V 4 and V 5 products using a 17 ga needle:

$$P_{AAL} = P_{AALS} + 75 - 0.331 Q_{ININSTD} / (1 - H_{IN}) - 0.303 Q_{ININSTD} (1 - 1/R) / (1 - H) - 350$$

where  $P_{AAL}$  is the ~~specified sensor pressure that triggers the first-level alarm;~~  $P_{AALS}$  is the ~~specified first-level alarm system pressure, mmHg;~~  $H_{IN}$  is the ~~inlet pump hematocrit, decimal;~~  $Q_{ININSTD}$  is the ~~instantaneous inlet pump flow for the draw phase, ml/min;~~ and  $R$  is the ~~ratio of whole blood to anticoagulant during platelet and plasma collection.~~

$$\text{specified sensor pressure} = \text{Config} + 75 - 0.3309 * Q_{in}/(1-H_{in}) - 0.3026 * Q_n/(1-H_n);$$

where Config is a configuration specified system pressure (mmHg.),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.

Please amend the paragraph beginning on page 29, line 25 as follows:

The configuration specified system pressure ~~specified first-level alarm pressure,~~  $P_{AALS}$ , should not be so high as to trigger false alarms, nor so low as to fall outside the capability of the sensor. Preferably, the configuration specified system pressure ~~specified first-level alarm pressure~~ is between about -100 to about -250 mmHg, and more preferably about -250 mmHg.

Please amend the paragraph beginning on page 31, line 13, as follows:

In a preferred embodiment, a return pressure alarm is provided. Too high a return pressure may indicate that blood is being sent somewhere else than the patient's vein, a condition which requires operator intervention to resolve. When the return pressure sensor senses a reading greater than a specified reading, a return pressure alarm is provided which stops the return pump as well as all other pumps and provides a signal to the operator. The sensor reading may be different from the actual pressure in the line, therefore, for the Gambro Trima® V 4 and V5 products using a 17 ga needle, the specified reading is calculated by the formula:

$$P_{RAL} = P_{RALS} - 50 - 0.3331 Q_{ININSTR} / (1 - H_{IN}) - 0.303 Q_{NRET} / (1 - H_{NRET}) = 400$$

~~where  $P_{RAL}$  is the change in sensor pressure that triggers the return pressure alarm, mmHg;  $P_{RALS}$  is the specified system return flow alarm triggering change in pressure, mmHg;  $Q_{ININSTR}$  is return the inlet pump flow, ml/min;  $H_{IN}$  is return the inlet pump hematocrit, decimal;  $Q_{NRET}$  is the flow rate through the needle during the single needle return phase, ml/min; and  $H_{NRET}$  is the hematocrit of the flow through the return needle.~~

specified sensor pressure = Config - 50 - 0.3309 \*  $Q_{in}/(1-H_{in})$  - 0.3026 \*  $Q_n/(1-H_n)$ ;

where Config is the configuration specified system pressure (mmHg),  $Q_{in}$  is the flow rate in the inlet tubing line (ml/min.);  $H_{in}$  is the Hematocrit in the inlet tubing line;  $Q_n$  is the flow rate in the needle (ml/min.); and  $H_n$  is the Hematocrit in the needle.